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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL M. LIEBERMAN

Appeal 2008-4415
Application 10/646,903
Technology Center 3700

Decided: December 11, 2008

Before DEMETRA J. MILLS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

Opinion for the Board filed by GREEN,
Administrative Patent Judge.

Opinion Concurring-in-part and Dissenting-in-part filed by FREDMAN,
Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal¹ under 35 U.S.C. § 134 from the Examiner's final rejection of claims 11 and 14-27. We have jurisdiction under 35 U.S.C. § 6(b).

¹ This Appeal was heard on November 20, 2008.

STATEMENT OF THE CASE

The claims are directed to a dual lumen catheter for treating a subdural hematoma, and a method for treating a subdural hematoma using a dual lumen catheter. Claims 11, 14, and 16 are representative of the claims on appeal, and read as follows:

11. An apparatus for use in medical procedures for treating subdural hematomas, the apparatus comprising a dual lumen catheter comprising, in combination:

- a drainage channel having a proximal portion and a distal portion; and
- an irrigation channel having a proximal portion and a distal portion

wherein said irrigation channel being disposed inside said drainage channel, said irrigation channel comprising a plurality of tubes each having one end coupled in fluid communication to said distal portion of said irrigation channel, each opposite end of said plurality of tubes coupled to said drainage channel so that said plurality of tubes support said irrigation channel inside said drainage channel while at the same time said plurality of tubes being dimensioned to deliver an irrigant from said irrigation channel to a subdural space.

14. A method for treating subdural hematomas comprising, in combination, the steps of:

- inserting a dual lumen catheter into a subdural space;
- draining said subdural space of a subdural fluid collection with said dual lumen catheter;
- and
- irrigating said subdural space using said dual lumen catheter.

16. A method for treating subdural hematomas comprising, in combination, the steps of:

- inserting a dual lumen catheter into a subdural space;
- draining said subdural space of a subdural fluid collection with said dual lumen catheter;
- irrigating said subdural space using said dual lumen catheter;
- providing a drainage channel having a proximal portion and a distal portion;

providing an irrigation channel having a proximal portion and a distal portion;

wherein said drainage channel and said irrigation channel comprise said dual lumen catheter;

draining said subdural space of subdural collection fluid through perforations defined by said drainage channel; and

irrigating said subdural space through perforations defined by said irrigation channel while draining of said subdural space by said drainage channel is performed.

The Examiner relies on the following references:

Wild

US 6,605,036 B1

Aug. 12, 2003

A. Dardik et al., *Subdural hematoma after thoracoabdominal aortic aneurysm repair: an underreported complication of spinal fluid drainage?*
36 J. VASC SURG. 47-50 (2002).

Declaration under 37 CFR 1.132 of Dan Lieberman, M.D. filed 20 February 2007.

We reverse.

ISSUE

The Examiner finds that claims 11 and 14-25 under 35 U.S.C. § 102(e) as anticipated by Wild.

Appellant contends that Wild:

1) Does not teach a dual lumen catheter wherein the irrigation channel comprises a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes coupled to the drainage channel so that said plurality of tubes support the irrigation channel inside the drainage channel

while at the same time the plurality of tubes being dimensioned to deliver an irrigant from said irrigation channel to a subdural space; and

2) Does not teach inserting a dual lumen catheter into a subdural space to drain it of fluid.

Thus, the issues on Appeal are:

1) Does Wild teach a dual lumen catheter wherein the irrigation channel comprises a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes coupled to the drainage channel so that said plurality of tubes support the irrigation channel inside the drainage channel while at the same time the plurality of tubes being dimensioned to deliver an irrigant from said irrigation channel to a subdural space; and

2) Does Wild teach inserting a dual lumen catheter into a subdural space to drain it of fluid?

FINDINGS OF FACT

FF1 The invention is drawn to a dual lumen catheter, which may be used to treat subdural hematomas (Spec. 7).

FF2 Figure 5 of the instant Specification is reproduced below.

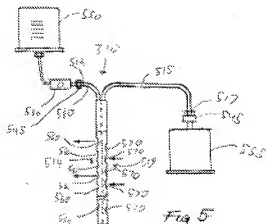


Figure 5 shows “a detailed view of the dual lumen catheter of the present invention with an irrigation container and a drainage container in accordance with one embodiment of the present invention.” (*Id.* at 5.)

FF3 The figure shows a dual lumen catheter, 310, comprising a drainage channel 515 having a proximal portion 517 and a distal portion 519 (*id.* at 7). The catheter 310 also comprises an irrigation channel 510, having a proximal portion 512 and a distal portion 514 (*id.*). The distal portion of the drainage 519 channel may have drainage perforations 570, and the distal end of the irrigation channel, 514, defines irrigation perforations 560 (*id.* at 8).

FF4 Figure 6B of the present application is reproduced below.

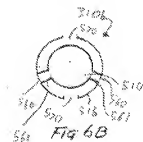


Figure 6B shows a dual lumen catheter of the present invention wherein an irrigation channel is disposed within the drainage channel (*id.* at 5). As

shown by the figure, the irrigation channel 510 is disposed inside the drainage channel 515 (*id.* at 10).

The irrigation channel 510 comprises a plurality of tubes 561, each having one end coupled in fluid communication to the distal portion 514 of the irrigation channel with an opposite end coupled to the drainage channel 515 so that the plurality of tubes 561 support the irrigation channel 510 inside the drainage channel 515 while at the same time the tubes 561 are dimensioned to deliver an irrigant from the irrigation channel 510 to a subdural space 125.

(*Id.*)

FF5 The Examiner rejects claims 11, and 14-25 under 35 U.S.C. § 102(e) as being anticipated by Wild (Ans. 3).

FF6 The Examiner finds that “Wild teaches a method and apparatus for treating a subdural hematoma (Col 1 line 53) comprising a dual lumen catheter (1) with a passive drainage channel (10) with perforations (at distal end) and multiple irrigation channels (9) with perforations (at distal end).”

(*Id.*)

FF7 Specifically, as to claim 11, the Examiner points to Figure 17 of Wild, finding that Figures 17a and 17b shows an arrangement of drainage tubes 10 and irrigation tubes 9 are disposed in bundle 3a (*id.* at 5). According to the Examiner, the bundle 3a and the lumen 10 read on the “drainage channel,” thus the lumens 9 are within the drainage channel and give support (*id.*).

FF8 As to claim 14, the Examiner finds that “Wild’s use of irrigation fluid to clear debris from the lens of the endoscope meets the limitation of ‘irrigating said subdural space.’ The drainage channel is passive and uses gravity to drain fluids, and is therefore always open and draining either the irrigate or the subdural fluid (Col 7 line 45-end).” (*Id.* at 6.)

FF9 Wild discloses a surgical instrument assembly “for use in endoscopic surgery, particularly endoscopic neurosurgery.” (Wild, col. 3, ll. 4-5.)

FF10 Figure 17 of Wild is reproduced below.

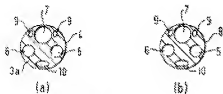


FIG. 17

Figure 17 shows a transverse view of the shaft of the surgical instrument of Wild (Wild, col. 11, ll. 1-3). Working channels 5 and 6 lie below the optical channel 7, and beneath them is a passive escape fluid channel 10 (Wild, col. 11, ll. 62-66). Two irrigation channels 9 provide clear fluid across the objective lens (col. 11, ll. 65-66). All the intervening space is filled with the integral fiber optic system 3 (col. 12, ll. 1-6).

FF11 Thus, Figure 17 of Wild does not show a dual lumen catheter wherein the irrigation channel comprises a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes coupled to the drainage channel so that said plurality of tubes support the irrigation channel inside the drainage channel while at the same time the plurality of tubes being dimensioned to deliver an irrigant from said irrigation channel to a subdural space.

FF12 In addition, Wild does not specifically teach using the disclosed surgical instrument assembly in the treatment of a subdural hematoma, and does not specifically disclose using the instrument in the subdural space.

FF13 The only time Wild discusses the treatment of subdural hematomas is in the discussion of the prior art, wherein Wild states that “[s]uch [prior art] unifunctional instrument assemblies have found use in neurosurgery and other relatively complex procedures, including . . . drainage of chronic subdural hematomas.” (Wild, col. 1, ll. 50-53.)

FF14 In response to the rejection of the Examiner, Appellant has submitted a Declaration in Rebuttal. According to Dr. Lieberman, an endoscope is not used for the treatment of subdural hematomas as the “endoscope is a rigid device which limits entry under the bone flap to between approximately 1-2 millimeters,” whereas a catheter, which does not have a camera, such as that disclosed in the instant application, “is capable of being inserted approximately 5-10 centimeters under the bone flap.” (Declaration under 37 CFR § 1.132, dated February 20, 2007.)

FF15 In response to the Declaration, the Examiner asserts that “Wild specifically points out that his device may be rigid or flexible (Col 6 line 37).” (Ans. 6.)

PRINCIPLES OF LAW

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

ANALYSIS

As to claim 11, Appellant argues that

Wild fails to disclose the feature of an irrigation channel comprising a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes coupled to the drainage channel *so that the plurality of tubes support the irrigation channel inside the drainage channel while at the same time the plurality of tubes being dimensioned to deliver an irrigant from the irrigation channel to a subdural space.*

(App. Br. 10.)

Appellant argues, that as shown in Figure 17 of Wild, the irrigation channels 9 are not supported inside drainage channel 10. We agree, and find that Wild does not teach a dual lumen catheter wherein the irrigation channel comprises a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes coupled to the drainage channel so that said plurality of tubes support the irrigation channel inside the drainage channel while at the same time the plurality of tubes being dimensioned to deliver an irrigant from said irrigation channel to a subdural space (FF11). We thus reverse the rejection as to claim 11.

As to claim 14, all that is required are the steps of: 1) inserting a dual lumen catheter into a subdural space; 2) draining said subdural space of a subdural fluid collection with said dual lumen catheter; and, 3) irrigating said subdural space using said dual lumen catheter. In response to Appellant's Declaration stating that endoscopic instruments are not used in the subdural space as its rigidity limits its entry under the bone flap to between approximately 1-2 millimeters (FF14). The Examiner responds that Wild teaches that the instrument may be flexible, but does not present

scientific argument or point to evidence in the record rebutting the Declaration, and specifically the Declarant's statement that endoscopic instruments are limited to entry under the bone flap to between approximately 1-2 millimeters. Therefore, as Wild does not explicitly disclose the steps of claim 14, and as the Examiner has not provided a prima facie case that the method steps are inherently disclosed by Wild, we are compelled to reverse the rejection as to that claim as well.²

As the remaining independent claims are also method claims that require more steps than those required by claim 14, we are compelled to reverse the remaining independent claims as well.

The Examiner rejects claims 26 and 27 under 35 U.S.C. § 103(a) as being obvious over the combination of Wild and Dardik.

Dardik is merely relied upon to reach the limitations of claim 26 and 27, that is the duration of irrigation and drainage of the subdural hematoma (Ans. 4). Thus, Dardik does not remedy the deficiencies of Wild, and we are compelled to reverse this rejection as well.

CONCLUSIONS OF LAW

Thus, we find that

1) Wild does not teach a dual lumen catheter wherein the irrigation channel comprises a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite

² We understand the position of our dissenting colleague. But the dissent relies on a rationale that was not presented by the Examiner, and thus, in our view, constitutes a new ground of rejection.

end of the plurality of tubes coupled to the drainage channel so that said plurality of tubes support the irrigation channel inside the drainage channel while at the same time the plurality of tubes being dimensioned to deliver an irrigant from said irrigation channel to a subdural space; and that

2) Wild does not teach inserting a dual lumen catheter into a subdural space to drain it of fluid.

Therefore, we reverse the rejection of claims 11, and 14-25 under 35 U.S.C. § 102(e) as being anticipated by Wild, as well as the rejection of claims 26 and 27 under 35 U.S.C. § 103(a) as being obvious over the combination of Wild and Dardik.

REVERSED

cdc

Fredman, *Administrative Patent Judge*

I concur with the Majority with respect to their conclusions regarding claims 11 and 23-27.

I respectfully dissent from the Majority's analysis³ regarding claim 14 and therefore would affirm the Examiner's rejection of claims 14-22 under 35 U.S.C. § 102(e).

Issue

Does Wild teach inserting a dual lumen catheter into a subdural space to drain it of fluid?

Principles of Law

“A preamble is not limiting, however, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Symantec Corp. v. Computer Associates Int’l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008) (internal quotations omitted) (quoting *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002)).

“A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation.” *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). In *Cruciferous Sprout*, the court stated “[i]t is well settled that a prior art reference may anticipate when the claim limitations not expressly found

³ The majority indicates that my reasoning differs from that of the Examiner. I think my reasoning is the same, though I do point to evidence in Wild to explain what is meant by “endoscopic neurosurgery” to address the Lieberman declaration (*see* Ans. 5).

in that reference are nonetheless inherent in it.” *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed. Cir. 2002).

Additional Findings of Fact

FF16 Wild teaches “[n]euroendoscopic surgery shows a wealth of potential as a neurosurgical technique” (Wild, col. 1, ll. 59-60).

FF17 Wild teaches that the instrument should be fixed and “may alternatively be anchored to the skull in adults” (Wild, col. 7, ll. 28-29).

FF18 Wild teaches that the surgical device contains “a passive fluid escape channel to allow drainage of fluid and debris from out of the operating zone. The passive fluid escape channel is connected proximally to a drainage tube providing gravity drainage and collection of all fluids” (Wild, col. 7, ll. 47-50).

FF19 Wild teaches that the device also comprises “[t]wo small further irrigation channels [which] are suitably further provided in the shaft of the support means . . . to enable a continuous flow of clear fluid across the field-collecting lens of the telescope, to remove debris from the field of view.” (Wild, col. 7, ll. 51-55).

FF20 Wild teaches that intracranial pressure is a concern when irrigating, noting that “[c]onventional control and fail-safe mechanisms are also provided to ensure that when irrigation fluid is used the intracranial pressure does not rise unduly.” (Wild, col. 7, ll. 55-58).

FF21 Dura mater is defined as the “the tough, fibrous membrane forming the outermost of the three coverings of the brain and spinal cord. Also called dura.”⁴

FF22 Subdural is defined as “the space between the strong outer layer of the Meninges, the membranes which cover the Brain, and the arachnoid, which is the middle layer of the meninges.”⁵

FF23 Hematoma is defined as “a circumscribed collection of blood, usually clotted, in a tissue or organ, caused by a break in a blood vessel.”⁶

FF24 Wild teaches that “[i]t is also desirable to avoid the necessity of direct transcerebral routes wherever possible and to adopt subarachnoid cisternal approaches to lesions within the head” (Wild, col. 8, ll. 3-6).

FF25 Wild teaches that “[n]euroendoscopy requires constant irrigation and this is particularly crucial in the presence of bleeding or debris” (Wild, col. 7, ll. 58-60).

Analysis

In my opinion, Wild persuasively teaches neuroendoscopic methods in which a dual lumen catheter is inserted into a subdural space (FF17, 21-24). In particular, Wild teaches that “[i]t is also desirable to avoid the

⁴ Dura mater. (n.d.). Dictionary.com Unabridged (v 1.1). Retrieved December 04, 2008, from Dictionary.com website:
[http://dictionary.reference.com/browse/dura mater](http://dictionary.reference.com/browse/dura%20mater).

⁵ Subdural. (2006). In *Black's Medical Dictionary, 41st Edition*. London: A&C Black. Retrieved December 04, 2008, from
<http://www.credoreference.com/entry/5878722>.

⁶ Hematoma. (n.d.). Dictionary.com Unabridged (v 1.1). Retrieved December 04, 2008, from Dictionary.com website:
<http://dictionary.reference.com/browse/hematoma>.

necessity of direct transcerebral routes wherever possible and to adopt subarachnoid cisternal approaches to lesions within the head” (Wild, col. 8, ll. 3-6; FF22). Since the arachnoid membrane layer is below the dura layer in the brain, it is physically impossible for Wild to place the catheter in the subarachnoid layer without inserting the catheter through the subdural space (FF21-22). Wild teaches that the catheter, when in use, will both drain and irrigate the space in order to remove debris, including bleeding (FF18-20, 25).

Since a subdural hematoma involves bleeding into the subdural space, when Wild inserts the dual lumen catheter into the brain with irrigation and drainage, passing through the subdural space, Wild inherently satisfies the limitations of claim 14 (FF17-25). In fact, Wild expressly teaches that blood is removed by the catheter (FF25). Since a hematoma is “a circumscribed collection of blood” (FF23), removal of the blood inherently represents treatment of a hematoma.

The Majority relies upon Appellant’s Declaration to find that “endoscopic instruments are not used in the subdural space as its rigidity limits its entry under the bone flap to between approximately 1-2 millimeters (FF14)” (Maj. Opinion 9). However, Wild clearly teaches that the endoscope is placed into the subarachnoid space, which is the layer below the dura, so that the endoscope passes through the subdural space in order to reach the subarachnoid space (FF21-24).

I also do not find persuasive Declarant’s argument that the “use of fluid described in the Wild patent is not for purposes of irrigating and draining a subdural space, but rather to continuously clear debris from the

optical lens of the telescope” (Lieberman Declaration ¶ 3). This argument is not consistent with claim 14, which simply “draining said subdural space of a subdural fluid collection” and “irrigating said subdural space using said dual lumen catheter.” Wild’s teaching to remove the blood and debris in the subdural space, which fouls the optical lens of the telescope, clearly satisfies the manipulative steps of claim 14. Wild drains subdural fluid and Wild irrigates the subdural space (FF18-25). In particular, Wild recognizes that intracranial pressure, caused by excessive irrigation, is a danger and when the catheter is inserted through the subdural space into the subarachnoid space, some of the irrigation liquid will inherently enter the open subdural space (FF20, 22-24).

In my opinion, *MEHL* supports the Wild rejection, noting “[i]t is not a question of probabilities as to whether a person of ordinary skill following the teachings of the article will align the laser light applicator over a hair follicle.” *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999). The radiation in *MEHL* was not focused on hair follicles, but was applied to the backs of guinea pigs. *Id.* While much of the radiation would not impact any hair follicle, the fraction which did was sufficient for the court to conclude that “[w]here, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article’s authors did not appreciate the results.” *Id.*

Just as in *MEHL*, it is a necessary consequence that insertion of the dual lumen catheter of Wild, with the consequent irrigation and drainage, will result in treatment of the subdural space to remove blood and other debris, resulting in treatment of any hematoma present (*see* FF19-25).

I do not find persuasive Appellant's argument that "[t]here is no discussion of using the Wild device for the treatment of subdural hematomas." (App. Br. 12.) In *Perricone*, the court found that "Pereira's disclosure of the topical application of the same composition necessarily anticipates claims 8, 9, and 13." *Perricone*, 432 F.3d at 1379. The court did not require evidence that Pereira had actually treated skin with the composition, only that Pereira disclosed the treatment. The court further found that regarding treatment of "aging skin," "[b]ecause Pereira discloses the very same composition and teaches its topical application, the district court correctly applied the inherency doctrine." *Id.* at 1380. Therefore, the *Perricone* court did not require actual treatment for inherent anticipation, and applying the same logic to the instant facts, I conclude that Wild inherently anticipates Appellant's claims.

Since I find that the Examiner has established a prima facie case of anticipation, I note that "after the PTO establishes a prima facie case of anticipation based on inherency, the burden shifts to appellant to 'prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" *In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986) quoting *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971). In my opinion, Appellant's have not satisfied this burden since the Lieberman Declaration does not explain how the endoscope of Wild can enter the subarachnoid space to treat lesions on the brain itself without first passing through the subdural space.

I would affirm the rejection of claims 14-22 under 35 U.S.C. § 102(e) as anticipated by Wild.

Appeal 2008-4415
Application 10/646,903

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